

Ser. No. 08/470,489

REMARKS

Applicants have canceled claims 42-49, 52-59, and 62-71. Claims 72-89 are new and find support in canceled claims 42-49, 52-59, and 62-71. In addition, support for these amendments is found in the specification. For instance, the hybridization conditions of claims 72 and 80 find support on page 27, ¶1, page 38, ¶2, and in Figure 9. Washing conditions find support on pages 54-55. Detection of HIV-2 DNA and RNA is supported on pages 24-25. Upon entry of this Amendment, claims 72-89 will be pending in this application.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 42-49, 52-59, and 62-71 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in such a way as to convey that the inventor(s) had possession of the claimed invention. The Office alleges that applicants' response failed to identify support for "probes that do not hybridize to nucleotides 2170-2240 and 5290-9130 of HIV-1."

Applicants traverse the rejection. In the response dated January 9, 1997, on page 8, ¶1, applicants referenced pages 46-47 of the specification as support for these amendments. However, solely to expedite prosecution of the application, applicants have canceled claims 42-49, 52-59, and 62-71. In accordance with the Office's suggestion as a means to obviate the rejection, new claims 72-89 do not recite this limitation. Accordingly, applicants respectfully request withdrawal of this rejection.

Ser. No. 08/470,489

Claims 42-49, 52-59, and 62-71 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly not enabling one to make/use the invention commensurate in scope with the claims. Specifically, the Office contends that the specification does not provide any guidance pertaining to the selection of probes that would function in the recited method.

Applicants traverse the rejection for the reasons asserted in the Amendment filed January 9, 1997. However, solely to expedite prosecution of the application, applicants have canceled claims 42-49, 52-59, and 62-71.

The Federal Circuit has stated the test for the enablement requirement of 35 U.S.C. § 112, first paragraph:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). New claims 72-89 recite that probes are selected that hybridize to a greater extent to the RNA/DNA of HIV-2 than to the RNA/DNA of HIV-1 BRU under specified hybridization conditions. Applicants submit that one skilled in the art expects that any probe selected in this manner functions in the recited method, absent evidence to the contrary. Since the disclosure provides adequate guidance for the skilled artisan to determine, without undue experimentation, which probes among all those encompassed by the claimed invention possess the disclosed properties, the claims are enabled with respect to the requirements of 35 U.S.C. § 112.

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Ser. No. 08/470,489

The Office also contends that applicants' claims should recite hybridization and washing conditions. Applicants traverse the rejection for the reasons asserted in the Amendment filed January 9, 1997. However, solely to expedite prosecution of the application, applicants have canceled claims 42-49, 52-59, and 62-71. New claims 72-89 recite typical hybridization and washing conditions. Accordingly, applicants respectfully request withdrawal of the rejection.

Finally, the Office contends that one skilled in the art could not generate the cDNA corresponding to the full-length viral genome, *gag*, *pol*, or *env* from the teachings of the specification. The Office further contends that the term "cDNA" is defined in the art as a double-stranded DNA sequence obtained by the in vitro enzymatic conversion (via reverse transcriptase) of mRNA into double-stranded DNA. Applicants respectfully disagree.

Applicants respectfully submit that a cDNA is not defined by the enzymatic process by which it is created. Rather, a cDNA is a DNA molecule that is **complementary** to an RNA molecule. More specifically, a cDNA usually differs from a genomic DNA in that it lacks introns that disrupt the coding region. This feature facilitates the elucidation of the coding potential of a genomic DNA. In one instance, a cDNA molecule may be constructed from a genomic DNA by deletion mutagenesis to remove intron sequences. In another instance, a single-stranded DNA molecule may be a cDNA. Applicants submit that these molecules are cDNAs. Although the majority

Ser. No. 08/470,489

of cDNA molecules generated by skilled artisans are likely generated by the process described by the Office, the process is not a prerequisite for the generation of a cDNA.

Furthermore, during each replication cycle, the genomic DNA of HIV-2 is generated by the process described by the Office. The completion of the LTR sequences is a duplication event that does not add any additional genetic material.

Therefore, the DNAs of genomic libraries of HIV-2 are cDNAs.

Indeed, applicants teach in the specification that HIV-2 creates a full-length cDNA during each replication cycle. (Specification at page 33, lines 8-12.) Absent evidence to the contrary, statements in the specification must be taken as true. *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971). Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 42, 49, 52, 59, 62, and 69 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 83 of copending application Serial No. 08/250,103. Applicants traverse the rejection.

Applicants have amended the claims to recite typical hybridization conditions. Applicants submit that claim 83 of copending application Serial No. 08/250,103 is not drawn to a method of detecting HIV-2 and does not include all of the recitations of the amended claims. Accordingly, applicants respectfully request withdrawal of the rejection.

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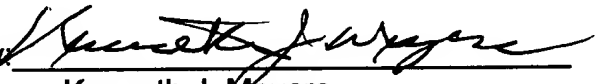
Applicants respectfully submit that entry of this Amendment puts this application in condition for allowance. Accordingly, applicants respectfully request entry of this Amendment and timely issuance of a Notice of Allowance.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136, not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Date: January 9, 1997

By 
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